

REMARKS

A Petition requesting a One (1) Month Extension of Time pursuant to 37 CFR §1.136 is attached hereto, along with the requisite fee.

The above-captioned patent application has been carefully reviewed in light of the final Office Action to which this Amendment is responsive. Claim 1 has been amended to include the subject matter of Claim 55, now canceled, so as to further particularly point out that which is regarded as the present invention. It is believed no new matter has been added.

Elected Claims 1-12, 17-20, 22, 23, 25, 53 and 55 are presently under examination, wherein the remaining pending Claims 13-16, 21, 26-52 and 54 have been withdrawn based on a prior Restriction Requirement. All of the elected claims stand rejected on prior art grounds. More specifically, Claims 1, 2, 6-12, 17, 18, 23, 53 and 55 have been rejected under 35 USC §103(a) as being unpatentable over Buechler (U.S. Patent No. 6,767,510) in view of Ohman et al. (WO 03/103835), Claims 3-5 and 25 stand rejected under 35 USC 103(a) based on the combination of Buechler, Ohman et al and Doshi et al (US Patent No. 5,660,798) and Claims 19, 20 and 22 stand rejected under 35 USC 103(a) based on the combination of Buechler, Ohman et al and Diamond (U.S. Patent Application Publication No. 2002/0142351). Applicants respectfully traverse each of the above rejections in light of the amended claims as well as the following remarks.

First and in order to successfully maintain a "*prima facie*" obviousness rejection under the Patent Statute, each and every claimed limitation must be found in or suggested by the cited prior art, either singly or in combination. Those limitations that are neither found in nor suggested by the prior art must be notoriously well known at the time of the invention to one of sufficient (ordinary) skill in the field thereof. In assessing references in terms of a purported combination, it is necessary to find a reason in the prior art as a whole. Such reasoning cannot come from advance knowledge (hindsight) of the present invention. To that end, if a suggested combination destroys the teachings of a reference

or otherwise renders a reference inoperable, this would be objective contrary evidence that "teaches away" from the claimed invention.

Applicants have now added the subject matter of Claim 55 into the sole pending independent Claim 1 and further amended Claim 1 in order to more particularly point out the present invention. The Examiner believes that Buechler relates to an open system or a system having an "open" flow path, referring to Figure 2 of this primary reference for support. Applicant disagrees with this characterization. As is clear from Fig. 2 of Buechler among other embodiments shown, a transparent cover or lid, labeled with reference numeral 8, is provided. Referring to col 7, lines 56-59 of this reference, "[t]he devices are comprised of capillary channels which are formed when a top member 8 is placed on the bottom member 9 a capillary distance apart and which move the reagents and sample throughout the device. The top and bottom members may be married, the various chambers sealed and the capillaries formed by a number of techniques, including but not limited to, gluing, welding by ultrasound, riveting and the like." Therefore, Buechler requires a "closed" system; one necessarily requiring a cover or lid in order to induce capillary action. Several of the embodiments of Buechler include drawings in which no lid is specifically shown; however, Applicants believe this lack of inclusion is for increased clarity of the drawings and is not intended to detract from the overall teachings of this reference requiring same. That is to say, Applicants believe each described embodiment of Buechler requires the presence of opposing surfaces in order to create (or induce) a capillary force in an assay device. Further evidence is found in Buechler for "closed" devices, irrespective of their geometry; see for example, col 4, lines 11-13; col 15, lines 62-65; col 16, lines 64-67; col 17, lines 35-55; col 18, lines 41-44; col 22, lines 5-8 and col 26, lines 10-14.

The present invention, on the other hand, can optionally, see page 24, lines 29-32, include a cover or lid as part of the overall device but such structure is not required to induce lateral capillary flow along the defined flow path. That is, lateral capillary flow may be solely induced based upon the characteristics of the first and second projections and based upon the open structure of the device. See page 24, lines 19-21.

The open flow path created by the present invention creates a number of advantages and features including simplification in manufacture, since no opposing surface has to be specifically positioned at a capillary distance, as required by Buechler, this step requiring a relatively high amount of precision and time. An added advantage is that the present device does not require the use of vents for permitting gas to escape, as is required in reactive systems, such as those described by Buechler.

There are additional differences between this primary reference and Claim 1. For example, the filter element in or on the sample addition reservoir that is described by Buechler and relied upon by the Examiner (see col 9, lines 3-7, col 24, lines 54-61 and col 36, lines 23-31) is a filter consisting of, for instance, nitrocellulose, cellulose, nylon, porous polypropylene, and polyethylene. In the latter noted reference at col 36, Buechler refers to other documents, including US 08/704,804 (now US 6,391,265), regarding the filter that is provide in the sample addition reservoir. A careful review of the '265 patent, however, fails to provided any teaching or suggestion of a separator filter element consisting of projections as presently claimed according to Claim 1.

Moreover, it is believed that a separator element comprising projections forming a gradient in an open system is radically different as compared to a filter in a system requiring opposing surfaces, such as described by Buechler. In a system with opposing surfaces, the filter does not have to create a capillary force since the capillary force is created by the opposing surfaces that are set at the capillary distance. In the present invention, however, a driving lateral capillary force must be created by the filter in order to drive the flow of sample liquid. In addition, the filter described in Buechler is very different from that presently claimed since it can comprise a porous material, see col 24, line 60. The filter (projections) of the present invention does not comprise a porous material.

As to the combinability of Buechler with Ohman et al. to re-create the claimed invention, Applicants believe that a person of sufficient skill in the field would not have considered the teachings of Ohman to incorporate a gradient of projections as discussed therein into the Buechler device(s), since: 1) the filter of Buechler, as previously noted, is considerably different in that the Buechler filter does not have to create (induce) a driving lateral capillary force. As noted, the filter in Buechler may comprise a porous material, whereas the projections of Ohman are not porous; 2) Buechler fails to teach or otherwise suggest that the filter itself may consist of projections; 3) Buechler fails to mention or otherwise indicate that a gradient filter is suitable; and 4) it would have destroyed the teachings of Buechler to implement a filter in the shape of a gradient of projections into this device. The filter projections would have to extend across the entire space between the opposing surfaces in order to be effective. This would require high precision in the manufacture and hence be difficult to implement.

For the foregoing reasons, Applicants believe the cited prior art is inapplicable to render the claimed invention obvious in that there is insufficient motivation to combine the references in the manner opined by the Examiner, absent hindsight. Even assuming their combination (which Applicants do not), it is still believed this combination would fail to completely disclose the presently claimed invention according to Claim 1. Claims 2, 6-12, 17, 18, 23, 53 are believed to be allowable for the same reasons. Reconsideration is therefore respectfully requested.

The additional references of Doshi et al. (U.S. Patent No. 5,660,798) and Diamond (U.S. Patent Publication No. 2002/0142351) have been cited by the Examiner only with regard to ancillary features of the claimed invention. Neither of these references, either singly or by way of combination, includes the features from Claim 1 that are entirely missing from Buechler and Ohman. Therefore, it is believed each of Claims 3, 5, 19, 20, 22 and 25 are also allowable over the prior art of record. Reconsideration is respectfully requested.

In summary, it is believed the pending claims are in an immediate condition for allowance. Furthermore, it is believed that the herein described amendment fails to add new issues or requires an additional search in that the amendment relates to the addition of previously searched subject matter and otherwise only provides clarity. Pursuant to 37 CFR §1.116, entry of this Amendment is respectfully requested. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to contact the undersigned at the telephone number listed below.

In the event that Applicants have overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefore and authorize that any charges be made to Deposit Account No.: 50-3010.

Respectfully submitted,

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